

### **REMARKS**

The Final Office action dated October 29, 2009 is acknowledged. The Applicants thank the Examiner for entry of the replacement drawings into the application. Claims 1-9 and 11-30 are pending in the instant application. According to the Final Office action, each of claims 1-9 and 11-30 are rejected. By the present response, claims 1 and 11 have been amended. Claim 1 has been amended solely for a slight clarification matter and claim 11 has been amended to depend from claim 1 rather than claim 10. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

#### **Rejection of Claim 11 under 35 U.S.C. 112, second paragraph**

Claim 11 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. In particular, the Examiner notes that claim 11 depends on canceled claim 10. Claim 11 has been amended accordingly. Withdrawal of this rejection is thus appropriate.

#### **Rejection of Claims 1, 2, 5, 12, 22 and 23 under 35 U.S.C. 102(b)**

Claims 1, 2, 5, 12, 22 and 23 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,765,348 (Honeycutt). The Examiner states that Honeycutt teaches each and every limitation of the aforementioned claims. In particular, the Examiner states that Honeycutt teaches a device for the administration of nicotine to the human body by inhalation (column 1, lines 37-45) for the purpose of being a non-combustible simulated cigarette (column 1, lines 8-10), wherein the device comprises a first preparation (18) containing a free base of nicotine (column 1, lines 45-46) contained

in a polytetrafluoroethylene matrix (column 3, lines 11-18) and a second preparation (20) containing a volatile acid (column 1, lines 46-52), such as acetic acid (column 2, line 39), which is separated from the first preparation (18) by an impermeable partition (24) (column 2, lines 48-49). The Examiner further states that the device contains a first air inlet, located to the right of section 18 in Figure 3, directing an inhaled airstream into an oblong air supply channel around section 18 in Figure 3, a second air inlet located to the right of section 20 in Figure 3 directing an inhaled airstream into an oblong air supply channel around section 20 in Figure 3, a common flow path (22) where the two airstreams from the separate sections combine simultaneously due to inhalation, and an outlet aperture (16) to where the common flow path leads (column 2, lines 60-69).

The Applicant respectfully disagrees with the Examiner's assessment of the presently claimed invention in view of Honeycutt. It is respectfully submitted that Honeycutt fails to disclose each and every limitation of the presently claimed invention as the claims are currently amended. As noted in the previous response, Honeycutt teaches a non-combustible simulated cigarette inhaler device which includes a hollow cylindrical tube having an open air inlet and an opposed open air outlet. Two elements of absorbent air permeable material are located within the hollow tube. The first element of absorbent air permeable material is located across a segment of the transverse cross-sectional area of the tube and is impregnated with a nicotine-free base material. The other element of absorbent air permeable material is located across the remaining segment of the transverse cross-section of the tube, and is impregnated with an acid which is reactive with the free base.

The term "impregnated" means that the materials of the first and second element

are coated or covered with the nicotine free base or acid. Thus, the nicotine free base or acid is absorbed to the surface of the materials of the first and second material. It is submitted that one skilled in the art would recognize that the term “impregnated” does not in any way include the incorporation of either the basic active agent or acid into the materials of the first or second element. Moreover, it is further submitted that the aforementioned is true since those skilled in the art are aware of the fact that, (1) the materials that are used for the first or second element include cotton, cellulose acetate, granulated charcoal, granulated polytetrafluoroethylene (column 2, lines 57-60) and, (2) there is no method described therein how to incorporate, i.e., disperse or merge, the active agent with these polymers.

Thirdly, the presently claimed invention is directed to specific polymers that are used for the preparation of the polymer matrix. These polymers include polyethylene, polypropylene, silicon polymers and polymethacrylates. Honeycutt does not teach or disclose any one of these polymers. Thus, the presently claimed invention is further distinguished from the teachings of Honeycutt in the choice of polymer materials that are used for the incorporation of basic active agents or acids.

Therefore, the presently claimed invention is clearly not anticipated by Honeycutt. Moreover, the presently claimed invention displays unexpected results in view of the prior art, as discussed below.

Upon using the device of the presently claimed invention, air flows over the preparation consisting essentially of the specific polymers and the nicotine base or the acid which is contained in a polymer matrix (paragraph [00058], [000067], for example). The nicotine base and the acid are released from the polymer matrices into the air stream.

Having the nicotine base, another basic active agent and/or volatile acid incorporated into the specific polymer materials rather than absorbed to the surface of a different material, it is possible to increase the device load with nicotine and/or acid to provide a sustained release of nicotine base and volatile acid to the air flow such that the inhaler of the presently claimed invention better simulates the nicotine acquisition occurring by smoking of a conventional cigarette.

As also noted in the previous response, Honeycutt does not teach the incorporation of nicotine base or an acid into a polymer matrix for being released from the matrix to be inhalable after salt formulation.

In view of the above, the subject matter of proposed present claim 1 is not anticipated by Honeycutt since the reference fails to teach each and every limitation of the present claims. Therefore, Honeycutt clearly fails to teach or otherwise disclose every limitation of the present invention as set forth in the present claims and therefore fails to anticipate the present invention. Withdrawal of this rejection is respectfully requested.

**Rejection of Claims 3, 4, 6-9, 13-21, 24 and 26- 30 Under 35 U.S.C. 103(a)**

Claims 3, 4, 9, 24, 25 and 27 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 4,284,089 (Ray). The Examiner states in the Final Office action that Honeycutt fails to teach the preparations containing a solvent suitable for inhalation. However, the Examiner refers to Ray for teaching a preparation containing water as a solvent, as well as menthol dissolved in ethanol as a flavoring (column 4, lines 23-28; column 7, lines 14-22) . Therefore, the Examiner concludes that it would have been obvious to one skilled in the art to provide the inhaler

of Honeycutt with solvents as taught by Ray in order to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

Claims 6, 7, 8, 14, 26, 28 and 30 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt. The Examiner argues that, regarding claim 6, Honeycutt teaches the chemical balance between volatilized nicotine and acid can be controlled (column 3, lines 1-10), but does not disclose the exact ratio of the chemical balance. However, the Examiner concludes that it would have been obvious to one skilled in the art that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

The Examiner also argues that, regarding claims 7, 8, 14, 26 and 30, Honeycutt discloses the claimed invention except for the inspiration duration, velocity, nicotine dose, particle size and negative pressure differential. The Examiner concludes that it would have been obvious to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully (column 3, lines 1-10) since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claim 28 and 29, the Examiner states in the Final Office action that Honeycutt discloses the device having an impermeable part (24) (column 2, lines 48-49) as well as discloses that the device can be made of any material (column 2, lines 11-13), but does not disclose a definite composition of the whole device. The Examiner concludes that it would have been obvious to one skilled in the art to make the entire device out of the impermeable material of impermeable partition (24) and for this material to be a polyester material coated with a copolymer, since it has been held to be

within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

Claim 29 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 5,400,808 (Turner). The Examiner states that Honeycutt does not disclose the material which is impermeable but argues that Turner teaches a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate (column 2, lines 36-41). Therefore, the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt of a material as taught by Turner to provide the advantage of a longer shelf life of the contents of the inhaler.

Claim 13 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 726,037 (Ferre). The Examiner states that Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. The Examiner refers to Ferre for teaching an inhaler with separate impermeable compartments (a, c) that have orifices (f) that can be opened or closed. Therefore, the Examiner concludes that it would have been obvious to one skilled in the art to provide the inhaler of Honeycutt with sealable compartments as taught by Ferre and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive disposable sealing means.

Claims 15-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt in view of U.S. Patent No. 5,660,169 (Källstrand, et al.). The Examiner argues that Honeycutt discloses the claimed invention except for a part formed by deep-

drawing. The Examiner argues that Källstrand, et al. disclose an inhaler device with an upper (1) and bottom part (2) containing a compartment with a peelable seal (Figs. 3a-c) formed by deep-drawing (column 2, lines 11-14). Therefore, the Examiner concludes that it would have been obvious to provide the inhaler of Honeycutt with deep-drawn components as taught by Källstrand, et al. in order to provide the advantage of an inexpensive way to manufacture the device.

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Applicant respectfully disagrees with the Examiner's conclusion set forth in the Office action for the numerous deficiencies of Honeycutt discussed above. Honeycutt fails to teach each and every limitation of the presently claimed invention, as discussed in detail above. Moreover, none of the cited secondary references make up for any of the numerous deficiencies of Honeycutt. Therefore, the combination of Honeycutt with the teachings of any of the secondary references fails to teach each and every limitation recited in the present claims.

It is therefore respectfully submitted that the present invention defined in the presently amended claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in Honeycutt alone or in

combination with the secondary references, nor would one skilled in the art be motivated to modify Honeycutt to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

### **Conclusion**

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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